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**MEMORANDUM**

**SUBJECT:** Environmental Risk Assessment for the Reregistration of Imazalil

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Attached please find the Environmental Fate and Effects Division's (EFED) environmental risk assessment for imazalil use as a seed treatment fungicide on wheat and barley. There are sufficient evidence with which to evaluate the fate characteristics of imazalil and to address uncertainties. The status of the environmental fate data submitted by the registrant is listed in Table 1. No additional environmental fate data are required at this time. However, based on the current data requirements for seed treatment chemicals, the registrant must submit an aquatic plant acute EC50 study using two species. Based on EFED's risk assessment, none of the RQ values trigger LOC exceedences for either terrestrial or aquatic non-target organisms, and minimal risk to the environment is expected. Imazalil is a plant sterol inhibitor and could possibly interfere with calcium metabolism in birds, though no eggshell thinning was observed in an avian chronic study.

**Table 1. Status of environmental fate data requirements for imazalil.**

Guideline #	Data Requirement	MRID/ Accession #	Classification	Is data requirement satisfied?
161-1	Hydrolysis	00248517	Acceptable	Yes
161-2	Photodegradation - water	40926701	Supplemental	Yes
162-1	Aerobic soil metabolism	00158160	Supplemental	Yes
162-2	Anaerobic soil metabolism	-	-	Waived*
163-1	Adsorption/desorption	00148072 00158160	Supplemental	Yes
164-1	Terrestrial field dissipation	-	-	Waived**
167-1	Seed leaching (special study)	-	-	Waived**

- Anaerobic soil metabolism data requirement is waived because the available fate data are sufficient to characterize the fate of imazalil in the environment.

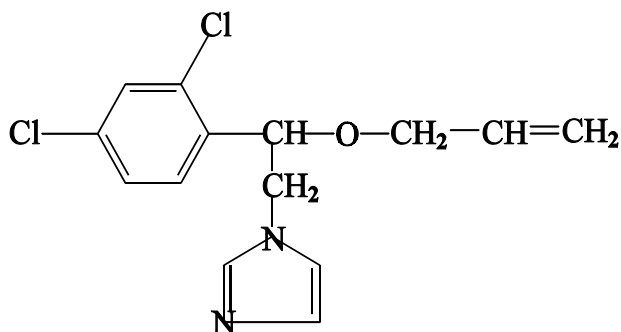
\*\* Terrestrial field dissipation and seed leaching data requirements are waived based on the results from Tier 1 exposure modeling.

**Table 2. Status of ecological effect data requirements for imazalil.**

Guideline #	Data Requirement	MRID/ Accession #	Classification	Is data requirement satisfied?
71-1	Avian acute oral LD <sub>50</sub>	00163243	Acceptable	Yes
71-2	Avian subacute dietary LC <sub>50</sub> bobwhite quail mallard duck	0030543 0030542	Acceptable Acceptable	Yes
71-4	Avian reproduction bobwhite quail mallard duck	41663801 42039801	Acceptable Acceptable	Yes Yes
72-1	Freshwater fish acute LC <sub>50</sub> rainbow trout bluegill sunfish	41606102 41606101	Acceptable Acceptable	Yes Yes
72-2	Freshwater invertebrate acute LC <sub>50</sub> (daphnia)	41606103	Acceptable	Yes
81-1	Acute mammalian oral LD50 (rat)	00031596	Acceptable	Yes
83-5	Two-generation mammalian reproduction (rat)	42570701	Acceptable	Yes
123-2	Aquatic plant acute EC50 (2 species)	-	-	No

## Environmental Fate and Ecological Risk Assessment for the Reregistration of Imazalil

(1-[2(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]- 1H-imidazole)



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## EXECUTIVE SUMMARY

The imazalil risk assessment showed that none of the RQ values triggered LOC exceedences for either terrestrial or aquatic non-target organisms, and minimal risk to the ecosystem is expected. Imazalil is a plant sterol inhibitor and could possibly interfere with calcium metabolism in birds. However, no eggshell thinning was observed in the avian chronic study.

Imazalil is immobile and relatively persistent under aerobic conditions. It is stable to hydrolysis and not expected to volatilize, but photodegrades rapidly in water. However, since the imazalil-treated wheat and barley seeds are buried in soil, photolysis is unlikely to play a major role in the dissipation of the chemical in the environment. In addition, its soil binding capacity suggest that imazalil is unlikely to move offsite by either leaching or runoff. Based on its octanol water partition coefficient, imazalil can accumulate in fish. However, since it is not expected to reach nearby surface waters at significant levels, the potential for this chemical to bioaccumulate in fish is very low.

Imazalil is acutely nontoxic to slightly toxic to birds. Chronically, it affects bird body weight, embryo viability, and hatchability. It is moderately toxic to mammals on an acute basis, and affected body weight and litter size in a chronic study. Based on limited data, it is moderately toxic to both freshwater fish and daphnids.

Imazalil is registered as a fungicide for seed treatment of small grains (wheat and barley), for post-harvest waxing of oranges, and as a disinfectant in chicken processing facilities. For seed treatment, the application rate is 0.01 lb a.i. per acre (maximum recommended rate), and only one application is allowed at planting time with one-inch soil incorporation. Seeds are pre-treated indoors using a liquid or ready-to-use formulation. The post harvest orange waxing is also conducted indoors via a dipping or spraying system and excess treated solution is drained back into a holding tank for reuse.

## INTRODUCTION

### Mode of action

Imazalil is an imidazole fungicide which is a sterol demethylation inhibitor (SDI). The mode of fungicidal action is to interfere with ergosterol synthesis of fungi by inhibiting the sterol C14 demethylation process. Physiologically, imazalil causes inhibition of gibberellic acid biosynthesis and production of demethylsterol in seedlings. In the demethylation process, the 14  $\alpha$ -methyl group in a sterol is removed by three NADPH-dependent oxygenase which is catalyzed by a cytochrom-p-450 enzyme. Imazalil, as a SDI, inhibits spore germination, activates uncoordinated chitin syntheses (which affects budding fungi), and accumulates free fatty acids (which is toxic to fungal cells).

### Use Characterization

Imazalil is an imidazole systemic fungicide. It is specifically effective in controlling seed- and soil-borne pathogens, such as *Pyrenophora*, *Fusarium*, and *Septoria* fungi. The use profile includes: 1) terrestrial feed crop (barley/wheat seed treatment), 2) indoor food (citrus fruits wax treatment), and 3) indoor non-food (egg hatching facilities and equipment disinfection).

Formulations of end products are emulsifiable concentrates, flowable concentrates, impregnated materials, and ready-to-use liquid products.

The major uses are (1) post-harvest treatment of citrus fruits, and (2) seed treatment of small grains. For the post-harvest citrus wax application, the 18-wheeler is backed into a packing house under an enclosed area. Overhead racks dribble down (via drip or spray system) treated water or soft edible wax on oranges on pallets at the back of the truck. Upon completion of the drench process, excess treated solution drains back into a holding tank, where it is filtered and sanitized for reuse. Wax application procedure is only practiced in Florida. Drenching only occurs during October through January.

Seed treatment of imazalil is limited to wheat and barley. Seeds are treated indoors commercially or on the farm. Typical commercial facilities for treating small grain seeds use standard mechanical slurry or mist type seed treatment equipment. The chemical is applied to the seed in a fully enclosed chamber and the application rate is regulated by the flow of seeds. The more sophisticated on-farm treaters are essentially miniature versions of the commercial treaters. Simpler units are mounted directly on a truck to dispense treated seeds directly into auger conveyance systems. The RTU (Ready-To-Use) products can obviate the need for making premixes in the field..

Recommended application rates are very low. For wheat and barley seed treatments, they are 0.005 lb. ai to 0.01 lb ai per 100 lbs. of seeds (100 lbs. of seed per acre). For citrus post-harvest treatment, imazalil concentrations for treatment solutions are 500 ppm for dipping and 750 ppm for drenching. The number of applications recommended is once per growing season both for citrus fruits and small grains seed treatment.

**Formulations and Application Rates:**

Product name	Formulation (lbs. a.i./gallon)	Label Rate (fl. oz./100 lbs seed)	Imazalil conc. on seed* (ppm)	Application rate (g a.i./A)
Fecundal 100 EC	0.85	0.8-1.5	52.4-98.3	2.14-4.01
Nu-Zone 10 ME	0.86	0.8-1.5	52.4-98.3	2.14-4.01
Flo Pro IMZ	2.84	0.25-0.5	55.5-111	2.27-4.53
RTU Vitavax Extra	0.1	5	39	1.59

**Chemical and Physical Properties**

Chemical name: 1-(2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl)-1H-imadazole  
Molecular formula:  $C_{14}H_{14}OCl_2$   
Molecular weight: 297.2  
Melting point: 52.7°C  
Vapor pressure (20°C):  $1.2 \times 10^{-6}$  mmHg  
Water solubility (20°C): 180 ppm  
Log octanol/water partition coefficient (Log<sub>ow</sub>): 3.82



## ENVIRONMENTAL FATE AND TRANSPORT ASSESSMENT

### Summary

Based on the environmental fate properties of imazalil, with consideration of the product formulation, the application methods, and the application rates, EFED believes that the immobile and relatively persistent parent compound is unlikely to have adverse effects on the environment.

Imazalil has the following characteristics:

- moderate water solubility (water solubility=180 ppm)
- very stable to hydrolysis at pH 5, 7, and 9
- photodegrades relatively rapidly with a half-life of 36 hours in water
- degrades very slowly in soil under aerobic conditions (half-life=166 days)
- immobile in soils ( $K_d$  ranged from 29-195 with an average of 130;  $K_{oc}$  ranged from 2,081-6,918 with an average of 4,324)
- not expected to volatilize (vapor pressure= $1.2 \times 10^{-6}$  mmHg; Henry's Law constant= $2.6 \times 10^{-9}$  atm m<sup>3</sup>/mol)
- high octanol water partition coefficient ( $K_{ow}$ =6,607).

### Abiotic Degradation

Imazalil does not hydrolyze at pH 5, 7, and 9 (Van Leemput, et. al.; 1982; Accession number 000248517). It photodegrades rapidly in the neutral aqueous environment (with a half-life of 36 hours; Van Leemput, et. al.; 1988; MRID 40926701). The photolytic fate of imazalil on the soil surface is unknown.

### Aerobic Soil Metabolism

Imazalil degraded relatively slowly in a loam soil with a half-life of 166 days (Van Leemput, et. al.; 1984; Accession number 00158160). Characterization of residues resulted in isolation of fraction FX which reached a maximum level (7% of the applied) at 70 days after application. This fraction was found to consist of two components. Component I was confirmed (by GC/MS) to be 1-[2-(2,4-dichlorophenyl)-2-hydroxyethyl]-1H-imidazole. The structure of component II was not confirmed. By the end of the study period (one year), 22% of the radioactivity had been mineralized to CO<sub>2</sub>. About 32% of the radioactivity was found to be soil-bound.

### Mobility

Based on the organic carbon adsorption coefficients ( $K_{oc}$ ) obtained from the adsorption studies, imazalil is classified as a chemical with a “low” soil mobility potential (average  $K_{oc}$  from 8 soils=4,324; average  $K_d$  from 8 soils=130; Van Leemput, et. al.; 1986; Accession number

00148072). The potential for the parent compound to move into ground water and to move with surface runoff water is very low. Listed below are the  $K_d$  and  $K_{oc}$  values:

Soil	Soil organic matter, %	$K_d$	$K_{oc}$
1	1.20	28.9	4151
2	6.63	80.0	2081
3	7.57	137.6	3134
4	4.68	187.8	6918
5	4.66	187.9	6951
6	4.18	110.0	4538
7	5.61	111.8	2915
8	8.63	195.3	3901
Average		129.9	4324

The mobility of  $^{14}\text{C}$ -labeled (at 2-ethyl carbon) imazalil was also evaluated in a soil column leaching study. Imazalil was found to be immobile in loam and sandy soils. The majority of imazalil remained in the top soil zone (95.7% of the applied was detected in the 0-2.5 cm zone for the loam soil column whereas 84.5% was detected in the same zone for the sand soil column). No residues were detected in the leachates.

### Bioconcentration

No study was conducted to evaluate the accumulation of imazalil in fish. Based on its high octanol water partition coefficient ( $K_{ow}=6,607$ ), imazalil is expected to accumulate in fish. However, the use of imazalil as a seed treatment for wheat and barley, along with its fate properties, mitigates the likelihood that this chemical will reach surface water and accumulate in fish.

### Water Resource Assessment

Imazalil is unlikely to contaminate surface and ground waters. Fate studies show that this chemical is immobile (average  $K_{oc} = 4,324 \text{ mL/g}$ ; average  $K_d = 130 \text{ mL/g}$ ) and is not expected to move offsite when used as a seed treatment. Both surface and ground water simulations (described below) show that imazalil may reach drinking water supplies only at very low concentrations.

## Surface Water

Surface water concentrations of imazalil were estimated with GENEEC. Input parameters for GENEEC (Table 3) were selected according to current EFED guidance. The peak concentration predicted by GENEEC is 0.072 ppb, while the 56-day average value is 0.037 ppb.

Table 3. GENEEC Input Parameters.

Parameter	Value
Application number per year	1
Application Rate	0.01 lb ai/acre
Aerobic Soil Metabolism Half Life	166 days
Aerobic Aquatic Half Life	n/a
Organic Carbon Partitioning Coefficient ( $K_{oc}$ )	2,081 mL/g (minimum)

## Ground Water

Ground water concentrations were predicted with SCI-GROW. Input parameters were chosen according to EFED current guidelines and are summarized in Table 4. The SCI-GROW output file is located in Appendix 2. The predicted groundwater concentration is negligible (0.0002 ppb).

Table 4. SCI-GROW input parameters for imazalil.

Parameter	Value
Application number per year	1
Application Rate	0.01 lb ai/acre
Aerobic Soil Half Life	166 days
Organic Carbon Partitioning Coefficient ( $K_{oc}$ )	4,026 mL/g (median Value)

## Drinking Water Recommendations

EFED has recommended that the Health Effects Division use the concentrations presented in Table 5 for drinking water EECs. .

Table 5. Drinking water estimated environmental concentrations for imazalil.

	56-day	Peak
Groundwater	n/a	negligible
Surface Water	0.037 µg/L	0.072 µg/L

## AQUATIC RISK ASSESSMENT

On the basis of risk quotients, the proposed use of imazalil on wheat and barley will not result in exceedences of highly acute, acute risk use, or acute endangered species of concern for freshwater organisms. Imazalil is moderately toxic to both freshwater fish and invertebrates in terms of acute toxicity (LC<sub>50</sub> range of 1.48 - 3.99 ppm for fish and EC<sub>50</sub> of 3.54 ppm for daphnids) (Table 6 ; Appendix 3). No acute levels of concern for freshwater organisms were exceeded due to the extremely low exposure, which is attributable to the low application rate (0.01 lb ai/A) and the seed treatment end-use (only 1% residue left on soil surface)(Table 7). Because of the extremely low exposure and relatively low acute toxicity to freshwater organisms, acute toxicity testing for estuarine aquatic organisms and all chronic testing have been waived.

**Table 6. Summary of acute toxicities for freshwater organisms exposed to imazalil.**

Species	96-hr LC <sub>50</sub> (ppm)	48-hr EC <sub>50</sub> (ppm)	Acute Toxicity (MRID)
Rainbow trout <i>Oncorhynchus mykiss</i>	1.48	--	moderately toxic (41606102)
Bluegill sunfish <i>Lepomis macrochirus</i>	3.99	--	moderately toxic (41606101)
Waterflea <i>Daphnia magna</i>	--	3.54	moderately toxic (41606103)

**Table 7. Acute EECs and risk quotients for freshwater fish and invertebrates exposed to imazalil.**

Crop Application Rate # of apps / interval	EECs	RQs	
	Peak (ppm)	Freshwater Fish LC <sub>50</sub> = 1.48 ppm	Freshwater Invertebrate LC <sub>50</sub> = 3.54 ppm
Wheat/barley 0.01 lbs. a.i./A One application at planting	0.00007	0.00005	0.00002

## TERRESTRIAL RISK ASSESSMENT

For the terrestrial risk assessment of imazalil seed treatment uses, the procedures for granular products with soil incorporation were used as a surrogate. Birds may be exposed to granular pesticides ingesting granules when foraging for food or grit. They also may be exposed by other routes, such as by walking on exposed granules or drinking water contaminated by granules. The number of lethal doses (LD<sub>50</sub>s) that are available within one square foot immediately after application (LD<sub>50</sub>s/ ft<sup>2</sup>) is used as the risk quotient for seed treatment of imazalil. Also, for the relative toxicity of treated seeds, risk quotients of number of treated seeds required to reach the

toxicity of LC<sub>50</sub> for various birds (i.e., no. seeds/LC<sub>50</sub>) are calculated. Risk quotients are calculated for three separate weight class of birds: 1000 g (e.g., waterfowl), 180 g (e.g., upland gamebird), and 20 g (e.g., songbird). For determination of an avian chronic RQ, the residual concentration in seeds is divided by the NOEC (i.e., EEC/NOEC) assuming that unlimited treated seeds are available without competition, and birds are feeding on nothing but these seeds.

Mammalian species also may be exposed to granular/bait pesticides (or treated seeds) by ingesting granules. They also may be exposed by other routes, such as by walking on exposed granules and drinking water contaminated by granules. The number of lethal doses (LD<sub>50</sub>'s) that are available within one square foot immediately after application and number of seeds require for LC<sub>50</sub> can be used as risk quotients (i.e., LD<sub>50</sub>'s/ft<sup>2</sup> and #seeds/LC<sub>50</sub>) for the various types of mammals exposed to bait pesticides. Risk quotients are calculated for three separate weight classes of mammals: 15 g, 35 g, and 1000 g. The mammalian chronic RQ for granivore species is calculated following the avian procedure. Based on the available data (Appendix 3), Imazalil is practically nontoxic to slightly toxic to birds, and moderately toxic to rats following the acute exposure. A chronic toxicity study with mallard ducks indicated effects on embryo viability and hatchability, while body weight loss was observed with bobwhite quails. In the two generation rat chronic study, effects on body weight, and litter size were observed (Table 8).

The acute risk quotients for both avian and mammal species exposed to imazalil are tabulated below.

**Table 8. Summary of acute and chronic toxicity data for terrestrial organisms exposed to Imazalil.**

Species	Acute Toxicity				Chronic Toxicity	
	LD <sub>50</sub> (Mg/ kg)	Acute Oral Toxicity (MRID)	5-day LC <sub>50</sub> (ppm)	Subacute Dietary Toxicity (MRID)	NOAEC/LOEC (ppm) (MRID)	Affected Endpoints (MRID)
Ring-necked Pheasant <i>Phasianus colchicus</i>	2000	slightly toxic 163243				
Northern bobwhite quail <i>Colinus virginianus</i>			> 5,620	practically nontoxic (30543)	250 /500 (41663801)	Body weight
Mallard duck <i>Anas platyrhynchos</i>	--	--	6290	practically nontoxic (30542)	250 /500 (42039801)	Embryo viability/ hatchability
Laboratory rat <i>Rattus norvegicus</i>	343	Moderately toxic 00031596	--	--	300/1200 (42570701)	Body weight reproduction

**Table 9. Acute and chronic risk quotients for avian species following exposure to imazalil applied at the proposed maximum application rates for wheat and barley.**

Crop Application Rate # of apps/interval	Bird type and Body weight (g)	% (decimal) of Pesticide Left on the Surface	Acute Risk Quotient				Chronic Risk Quotients
			Exposed mg/ft <sup>2</sup>	Adjusted LD <sub>50</sub> (mg/kg)	Acute RQ(LD <sub>50</sub> /ft <sup>2</sup> )	Acute RQ(#seeds / LC <sub>50</sub> )	Birds NOEC = 250 ppm
Wheat 0.01 lbs. a.i./A 1/season	Song bird (20)	0.01	0.001	40	0.00003	10000	0.4
	Upland Gamebird (180)	0.01	0.001	360	0.000003	90000	
	Waterfowl (1000)	0.01	0.001	2000	0.000001	500000	
Barley 0.01 lbs. a.i./A 1/season	Song bird (20)	0.01	0.001	40	0.00003	13333	
	Upland Gamebird (180)	0.01	0.001	360	0.000003	120000	
	Waterfowl (1000)	0.01	0.001	2000	0.000001	666666	

**Table 10. Acute and chronic risk quotients for mammals following exposure to imazalil applied at the proposed maximum application rates for wheat and barley.**

Crop Application Rate # of apps/interval	Body weight (g)	% (decimal) of Pesticide Left on the Surface	Acute Risk Quotient				Chronic Risk Quotients
			Exposed mg/ft <sup>2</sup>	Adjusted LD <sub>50</sub> (mg/kg)	Acute RQ(LD <sub>50</sub> /ft <sup>2</sup> )	Acute RQ(#seeds / LC <sub>50</sub> )	Birds NOEC = 300 ppm
Wheat 0.01 lbs. a.i./A 1/season	15	0.01	0.001	5.145	0.0002	1286	0.3
	35	0.01	0.001	12.005	0.0008	3001	
	1000	0.01	0.001	343	0.000003	85750	
Barley 0.01 lbs. a.i./A 1/season	15	0.01	0.001	5.145	0.0002	1715	
	35	0.01	0.001	12.005	0.0008	4002	
	1000	0.01	0.001	343	0.000003	114333	

RQ values of # of LD<sub>50</sub>/ft<sup>2</sup>, # of seeds/LC<sub>50</sub>, and EEC/NOEC, are all extremely low and no LOCs are exceeded. For # of LD<sub>50</sub>/ft<sup>2</sup>, only 0.00003 (max. # of bird LD<sub>50</sub>) to 0.0002 (max. # of mammal LD<sub>50</sub>) can be found in a square foot. Also, an extremely large number of seeds is required to reach an LD<sub>50</sub> dose (10000 seeds to 666666 seeds and 1286 seeds to 114333 seeds required for avian LD<sub>50</sub> and mammalian LD<sub>50</sub>, respectively (**Tables 9 and 10**)).

On the basis of risk quotients, imazalil use at the proposed application rate for wheat and barley will not result in an acute risk to either avian or mammal species. No LOCs were exceeded due to the low application rate and minimal exposure.

## ENDANGERED SPECIES

There is no endangered species concern because none of the acute or chronic RQ values exceeded LOCs.

## ENVIRONMENTAL RISK CHARACTERIZATION

Imazalil is registered as the fungicide for seed treatment of small grains (wheat and barley) and for post-harvest waxing of oranges. It can also be used as a disinfectant to sterilize chicken processing facilities by spraying or fumigation. For seed treatment, application rate is 0.01 lb a.i. per acre (a maximum rate), and only one application is allowed at planting time with one inch soil incorporation. As the result of soil incorporation, only 1 % of pesticide applied is expected to remain on the soil surface. Hence, its exposure to fish and wildlife is limited due to proposed indoor use and seed-treatment use with a low application rate.

The chemical is immobile and relatively persistent under aerobic conditions. It is stable to hydrolysis and is not expected to volatilize, but photodegrades rapidly in water. However, since the imazalil-treated wheat and barley seeds are buried in soil, photolysis is unlikely to play a major role in the dissipation of the chemical in the environment. In addition, its placement in the soil and its soil binding capacity suggest that imazalil is unlikely to move offsite by either leaching or erosion/runoff. Based on its octanol water partition coefficient, imazalil can accumulate in fish. However, since it is not expected to reach nearby surface waters at significant levels, the potential for this chemical to bioaccumulate in fish is very low.

Acute toxicity of imazalil ranges from practically nontoxic to slightly toxic to birds. Chronically, it affects bird body weight, embryo viability, and hatchability (NOAEC = 250 ppm). It is moderately toxic to mammals on acute basis, and affected body weight and litter size in a chronic study (NOAEC = 300 ppm). Based on the limited data, it is moderately toxic to both freshwater fish and aquatic invertebrates.

The granular approach is used to assess terrestrial ecological risk of residues on treated seeds. In granular pesticides, active ingredients are impregnated/mixed with the inert materials. These active ingredients are expected to be slowly released to inhibit pathogens, while with treated seeds, an active ingredient is coated tightly on the seed surface to protect seeds. Based on terrestrial RQ values, none of the LOCs is exceeded. Minimal risk is expected for terrestrial nontarget organisms.

For the aquatic ecological risk assessment, EEC values based on GENEEC model are used. The resulting LOCs are not exceeded. Should Tier II PRZM-EXAMS modeling be used, aquatic EECs would be greatly reduced. GENEEC predicts 10% of the pesticide applied to a 10 acres field will reach an one-acre pond via run-off. In the actual field conditions, less than one percent of applied will reach surface water because of the arid wheat growing environment.

Imazalil has a potential to cause endocrine effects in birds. In a classical case, DDT (DDE) caused eggshell thinning in birds by interfering with the calcium absorption via inhibition of sterol synthesis. Similarly, imazalil inhibits synthesis of ergosterol which is the precursor of Vitamin D<sub>2</sub> (also known as ergocalciferol). Deficiency of Vitamin D<sub>2</sub> will affect the absorption

of calcium cations from the intestine and could result in eggshell thinning (S. Grollman.1974. The Human Body, Its Structure and Physiology. MacMillan Publishing Co.). But, no evidence of eggshell thinning was observed in the submitted avian chronic study and this may be due to low residual level.

Results of imazalil ecological risk assessments show that none of the RQ values triggers the LOCs for either terrestrial or aquatic non-target organisms. The minimal risk to these organisms is expected. There is no fish or wildlife incident report found in EFED's Ecological Incident Information System. Also, there is no drinking water or ground water data for imazalil +in STORET. Imazalil is a plant sterol inhibitor and could possibly interfere with calcium metabolism in birds. However, no eggshell thinning was observed in the avian chronic study.

## **OUTSTANDING DATA REQUIREMENT**

With the exception of the aquatic plant growth data requirement (122-2), the environmental fate and effects data requirements are fulfilled. The aquatic plant growth data requirement (122-2) were waived previously. However, based on the current guidelines for seed treatment chemicals, the Tier I aquatic plant growth studies (122-2) with two species of aquatic plants ( *Lema gibba* and *Selenastrum capricornutum* ) are required.

## **ENVIRONMENTAL FATE DATA REFERENCES**

Van Leemput, L., E. Swysen, J. Hendrickx, M. Bockx, and J. Heykants. 1988. On the Photolysis of Imazalil in the Aquatic Environment. Janssen Research Foundation, Belgium. (MRID 40926701)

Van Leemput, L., R. Woestenborghs, L. Michielsens, W. Meuldermans, and J. Peeters. 1982. Hydrolysis as a Possible Mechanism of Dissipation of Imazalil. Janssen Pharmaceutica, Belgium. (Accession No. 000248517)

Van Leemput, L., E. Swysen, R. Firlefyn, W. Meuldermans, and J. Heykants. 1986. The Adsorption of Imazalil on Soil. Janssen Pharmaceutica, Belgium. (Accession No. 000262207)

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Van Leemput, L., E. Swysen, J. Hendrickx, W. Lauwers, W. Meuldermans, and J. Heykants. 1984. The Transformation of <sup>14</sup>C-imazalil in Watervliet loam, Incubated at 25C in Flow-through Soil metabolism systems. Janssen Pharmaceutica, Belgium. (Accession No. 000158160)

## **ECOLOGICAL EFFECTS DATA REFERENCES**

MRID 163243. Marsboom, R. 1986. Acute oral toxicity study in ring-necked pheasants, Imazalil. 97.5 % ai. Jensen Pharmaceutica Exp. No. 1601. Review by A. W. Vaughan (EPA). LD50 2000 mg/kg. Core.

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MRID 30542. Fink, R. and J. B. Beavers, 1979. Eight-Day Dietary LC50 - Mallard. 99.8 % ai. Wildlife International, Inc. Porj. No. 168-102. Reviewed by W. C. Faatz (EPA). LC50 >5620 ppm. Core.

MRID 416638-01. Van Cauteren, H., W. Coussement, J. Vandenbereghe, G. Teuns, and R. Marsboom. 1988. Reproduction study in bobwhite quails, 98.7 %. Janssen Pharmaceutica. Exp. No. 1822. Reviewed by M. L. Whittens (KBN). NOEC 250 ppm, LOEC 500 ppm(body weight). Core.

MRID 420398-01. Teuns, G., A., Lampo, W. Coussement, and H. Van Cauteren. 1991. Reproduction study in mallard ducks. 98.1 -98.5 %. Janssen Pharmaceutica. Exp. No. 2288. Reviewed by M. L. Whitten (KBN). NOEC 250 ppm, LOEC 500 ppm (embryo viability and hatch ability). Core.

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MRID 416061-01. Weytjens, D., P. Boonen, L. Van Leemput, R. Woestenborghs, and L. Michielen. 1988. The acute toxicity of Imazalil (R23979) for bluegill (*Lepomis macrochirus*). 97.6 % ai. Janssen Pharmaceutica. Report No. R23979/AF/LM/6. Reviewed by J. L. Kavanugh (KBN) LC50 3.99 ppm, NOEC 2.78 ppm. Core.

MRID 416061-03. Neytjens, D. and R. Wils. 1990. The acute toxicity of Imazalil (R23979) in the water-flea (*Daphnia magna*). 97.6 % ai. Janssen Pharmaceutica. Report No. R23979/AD/K6. LC50 3.54 ppm, NOEC 1.8 ppm. Core.

## **APPENDIX 1: Summary of Submitted Environmental Fate Studies**

### **1. Degradation**

#### **161-1 Hydrolysis**

The submitted study (Van Leemput, et. al.; 1982; Accession number 000248517) on the hydrolysis of imazalil was determined to be acceptable and the Hydrolysis (161-1) data requirement was considered fulfilled on 5/19/86.

Results from this study are summarized below:

"Imazalil sulfate at 20 ppm was stable to hydrolysis at pH 5, 7, and 9 after incubation at 25C for up to 61 days. Concentrations in the solution at days 0 and 61 were 19.6 and 20.5 ppm (pH 5), 18.5 and 19.8 ppm (pH 7), and 17.7 and 17.9 ppm (pH 9)."

#### **161-2 Photolysis in Water**

The submitted study (Van Leemput, et. al.; 1988; MRID 40926701) on the photodegradation of imazalil in water was determined to be supplemental on 10/18/89. On June 14, 1990, after reviewing the additional data submitted by the registrant, EFED concluded that this study is acceptable and the Photolysis in Water (161-2) data requirement is fulfilled. However, according to the current guidelines, this study is considered supplemental because the major degradates were not identified and the test substance was not labeled on the rings.

Results from this study are summarized below:

"The aqueous photolysis for 2-ethyl [14C]imazalil sulfate was studied by artificial sunlight irradiation (Hanau suntest xenon lamp) of 10 ppm solutions of 14C-imazalil sulfate in the pH 7 phosphate/citric acid buffer solution at 30C for 144 hours. The half life for imazalil was 36.1 hours in the pH 7 buffer solution. Two major degradates (F-1 and F-VII) were detected. Compound F-1 was first detected at 36 hours post treatment with a concentration of 3.7% of the applied and it reached the maximal concentration of 72.2% of the applied at 144 hours. The second compound, F-VII, was first detected at 24 hours with a concentration of 7.3% of the applied and it reached the maximal concentration of 17.8% of the applied. However, Compound F-VII became non-detectable at 144 hours. Less than 2% of the applied radioactivity was detected as CO<sub>2</sub>."

### **2. Metabolism**

#### **162-1 Aerobic Soil Metabolism**

The registrant submitted an aerobic soil metabolism study (Van Leemput, et. al.; 1984; Accession 00158160) to support the Aerobic Soil Aquatic Metabolism data requirement. This study was determined to be acceptable on 4/7/87. At the same time, the EFED concluded that this study can be used to fulfill the Aerobic Soil Metabolism data requirement. However, according to the current guidelines, this study is considered supplemental because the soil was not maintained at the required moisture (i.e, 75% of the field capacity) and the test substance was not labeled on the rings.

Results from this study are summarized below:

"A loam soil (sand 46.4%; silt 40.1%; clay 13.5%, organic matter 4.7%; pH 7.1; CEC 25.6 meq/100 g soil; origin: Belgium) spiked with 5 ppm 2-ethyl 14C-labeled imazalil sulfate was incubated at 25C in a flow-through system for one year. The soil was maintained at 50% of the water holding capacity. Imazalil degraded relatively slowly with a half-life of 166 days. Material balance ranged from 97% on Days 14 to 74% on Days 171. Characterization of residues resulted in isolation of fraction FX which reached to a maximum level (7% of the applied) at 70 days after application. This fraction was found to consist of two components. Component I was confirmed (by GC/MS) to be 1-[2-(2,4-dichlorophenyl)-2-hydroxyethyl-1H-imidazole. The structure of component II was not confirmed. By the end of the study period (one year), 22% of the radioactivity had been mineralized to CO<sub>2</sub>. About 32% of the radioactivity was found to be soil-bound."

### **3. Mobility/Leachability**

#### **163-1 Leaching-Adsorption/Desorption**

Two studies (Van Leemput, et. al.; 1986; Accession number 00148072, Van Leemput, et. al.; 1985; Accession number 00158160) were submitted to satisfy the Leaching-Adsorption/Desorption data requirement.

The first study (Van Leemput, et. al.; 1986) was determined to be acceptable and the batch equilibrium data requirement was considered fulfilled on 4/7/87. However, according to the current guidelines, this study is considered supplemental because all the selected soils contained organic matter greater than 1% and none of the soils were collected from the wheat and barley use areas in U.S.

Results from the first study are summarized below:

"2-Ethyl-14C-labeled imazalil sulfate (purity 99%, specific activity 10.1uCi/mg) at 0.1, 0.5, 1, 5, 10, and 50 ppm were mixed into a slurry consisting sand, sandy loam, loam, loam, silt loam, silt, and silty clay loam soils. The mixtures were shaken for 48 hours at 22-24C, centrifuged, and aliquots of supernatant was removed and analyzed using LSC. Freundlich K<sub>d</sub> values ranged from 28.9-195.3 in eight soils."

Soil	Soil organic matter, %	Soil organic carbon, %	K <sub>d</sub>	K <sub>oc</sub>
1	1.20	0.70	28.9	4151
2	6.63	3.85	80.0	2081
3	7.57	4.39	137.6	3134
4	4.68	2.71	187.8	6918
5	4.66	2.70	187.9	6951
6	4.18	2.42	110.0	4538

7	5.61	3.25	111.8	2915
8	8.63	5.00	195.3	3901
Average			129.9	4324

The second study (Van Leemput, et. al.; 1985; Accession number 00158160) was determined to be unacceptable on 2/3/86. After reviewing the information submitted by the registrant, the study was determined to be acceptable on 4/7/87. Although this study provides useful information on the soil mobility (leaching) of imazalil in two soils, this study is considered supplemental. The reasons are: (1) only 30 cm of water was applied; and (2) the soils were not collected from the wheat and barley use areas in U.S.

Results from this study are summarized below:

"The mobility of <sup>14</sup>C-labeled (at 2-ethyl carbon) imazalil sulfate (purity 99%) was evaluated in soil columns. A loam soil (sand 46.4%; silt 40.1%; clay 13.5%, organic matter 4.7%; pH 7.1; CEC 25.6 meq/100 g soil; origin: Belgium) and a sandy soil (sand 92.3%; silt 5.7%; clay 2.0%, organic matter 1.2%; pH 4.8; CEC 10.7 meq/100 g soil; origin: Belgium) were treated with <sup>14</sup>C-imazalil sulfate and leached with 30 cm of water for three days. Majority of imazalil remained in the top soil zone (95.7% of the applied were detected in the 0-2.5 cm zone for the loam soil column whereas 84.5% were detected in the same zone for the sand soil column). No residues were detected in the leachates."

## Appendix 2: SCI-GROW and GENEEC for Environmental Fate Assessment

### Background Information on SCI-GROW:

SCI-GROW provides a ground water screening exposure value to be used in determining the potential risk to human health from drinking water contaminated with the pesticide. Since the SCI-GROW concentrations are likely to be approached in only a very small percentage of drinking water sources, i.e., highly vulnerable aquifers, it is not appropriate to use SCI-GROW concentrations for national or regional exposure estimates.

SCI-GROW estimates likely ground water concentrations if the pesticide is used at the maximum allowable rate in areas where ground water is exceptionally vulnerable to contamination. In most cases, a large majority of the use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate.

### SCI-GROW Printout for Use of Imazalil on Wheat and Barley:

RUN No. 1 FOR Imazalil		INPUT VALUES		
APPL (#/AC) RATE	APPL. NO. (#/AC/YR)	URATE	SOIL KOC	SOIL AEROBIC METABOLISM (DAYS)
.010	1	.010	4026.0	166.0

#### GROUND-WATER SCREENING CONCENTRATIONS IN PPB

.000189

A= 161.000 B= 4131.000 C= 2.207 D= 3.616 RILP= .847  
F= -1.724 G= .019 URATE= .010 GWSC= .000189

### Background Information on GENEEC:

GENEEC is a screening model designed to estimate the pesticide concentrations found in water for use in ecological risk assessments. As such, it provides high-end values on the concentrations that might be found in ecologically sensitive environments due to the use of a pesticide. GENEEC is a single-event model (one runoff event), but can account for spray drift from multiple applications. GENEEC is hardwired to represent a 10-ha field immediately adjacent to a 1-ha pond, 2 meters deep with no outlet. The pond receives a spray drift event from each application plus one runoff event. The runoff event moves a maximum of 10% of the applied pesticide into the pond. This amount can be reduced due to degradation on field and the effects of binding to soil. Spray drift is equal to 1% of the applied concentration from the ground spray application and 5% for aerial application.

**GENEEC Printout for Use of Imazalil on Wheat and Barley:**

RUN No. 1 FOR Imazalil INPUT VALUES

RATE (#/AC) ONE(MULT)	APPLICATIONS NO.-INTERVAL	SOIL KOC	SOLUBILITY (PPM)	% SPRAY INCORP DRIFT	DEPTH(IN)
.010( .010)	1 1	2081.0	180.0	.0	1.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
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166.00	2	N/A	1.50-	184.05	.00 184.05
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GENERIC EECs (IN PPT)

PEAK GEEC	AVERAGE 4 DAY GEEC	AVERAGE 21 DAY GEEC	AVERAGE 56 DAY GEEC
72.06	68.16	52.35	37.14

## APPENDIX 3: ECOLOGICAL EFFECTS CHARACTERIZATION

### a. Toxicity to Terrestrial Animals

#### i. Birds, Acute and Subacute Toxicity

An acute oral toxicity study using the technical grade of the active ingredient (TGAI) is required to establish the toxicity of imazalil to birds. The preferred test species is either mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Result of this test with ring-necked pheasant is tabulated below.

##### Avian Acute Oral Toxicity

Species	% ai	LD50 (mg/kg)	Toxicity Category	MRID No. Author/Year	Study Classification <sup>1</sup>
Ring-necked Pheasant ( <i>Phasianus colchicus</i> )	97.5	2000	slightly toxic	163243 Marsboom/ 1986	Core

<sup>1</sup> Core (study satisfies guideline). Supplemental (study is scientifically sound, but does not satisfy guideline)

Since the LD50 falls in the range of 501-2000 mg/kg, imazalil is categorized as slightly toxic to avian species on an acute oral basis. The guideline (71-1) is fulfilled (MRID 163243).

Two subacute dietary studies using the TGAI are required to establish the toxicity of Imazalil to birds. The preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

##### Avian Subacute Dietary Toxicity

Species	% ai	5-Day LC50 (ppm) <sup>1</sup>	Toxicity Category	MRID No. Author/Year	Study Classification
Northern bobwhite quail ( <i>Colinus virginianus</i> )	99.8	> 5620	Practically nontoxic	30543 Fink & Beavers/1979	Core
Mallard duck ( <i>Anas platyrhynchos</i> )	99.8	6290	Practically nontoxic	305 42 Fink & Beavers/1979	Core

<sup>1</sup> Test organisms observed an additional three days while on untreated feed.

Since the LC50 is greater than 5000 ppm, imazalil is categorized as practically nontoxic to avian species on a subacute dietary basis. The guideline (71-2) is fulfilled (MRID 30542/30543).

#### ii. Birds, Chronic Toxicity

Avian reproduction studies using the TGAI are required for imazalil because the following conditions are met: (1) the pesticide is stable in the environment to the extent that potentially toxic amounts may persist in animal feed, (2) the pesticide is stored or accumulated in plant or animal tissues, and/or, (3) information derived from mammalian reproduction studies indicates reproduction in terrestrial vertebrates may be adversely affected by the anticipated use of the product. The

preferred test species are mallard duck and bobwhite quail. Results of these tests are tabulated below.

### Avian Reproduction

Species/ Study Duration	% ai	NOEC/LOEC (ppm)	LOEC Endpoints	MRID No. Author/Year	Study Classification
Northern bobwhite quail ( <i>Colinus virginianus</i> )	98.7	250/500	Body weight	41663801 Van Cauteren et al. 1988	Core
Mallard duck ( <i>Anas platyrhynchos</i> )	98.1-98.5	250/500	Embryo viability/ hatchability	42039801 Teuns et al./ 1991	Core

The guideline (71-4) is fulfilled(MRID 41663801/42039801).

### iii. Mammals, Acute and Chronic Toxicity

Wild mammal testing is required on a case-by-case basis, depending on the results of lower tier laboratory mammalian studies, intended use pattern and pertinent environmental fate characteristics. In most cases, rat or mouse toxicity values obtained from the Agency's Health Effects Division (HED) substitute for wild mammal testing. These toxicity values are reported below.

### Mammalian Toxicity

Species/ Study Duration	% ai	Test Type	Toxicity Value	Affected Endpoints	MRID No.
laboratory rat ( <i>Rattus norvegicus</i> )	95%	Acute oral	LD <sub>50</sub> = 343 mg/kg	Mortality	00031596
laboratory rat ( <i>Rattus norvegicus</i> )	95%	Reproductive (2-generation)	LOAEL = 1200 ppm NOAEC = 300 ppm	Body weight litter size Duration of gestation	42570701

An analysis of the result indicates that imazalil is categorized highly toxic to small mammals on an acute oral basis.

### iv. Insects Toxicity

A honey bee acute contact study using the TGAI is not required for imazalil because its use (seed treatment/post harvest orange waxing) will not result in honey bee exposure.

### v. Terrestrial Field Testing

Not required due to low toxicity and minimal exposure.



## b. Toxicity to Freshwater Aquatic Animals

### i. Freshwater Fish, Acute

Two freshwater fish toxicity studies using the TGAI are required to establish the toxicity of imazalil to fish. The preferred test species are rainbow trout (a coldwater fish) and bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

#### Freshwater Fish Acute Toxicity

Species/ Flow-through or Static	% ai	96-hour LC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Rainbow trout ( <i>Oncorhynchus mykiss</i> ) static	99.5	1.48	Moderately toxic	41606102 Weytjens & Wils 1989	Core
Bluegill sunfish ( <i>Lepomis macrochirus</i> )	97.6	3.99	Moderately toxic	41606101 Weytjens et al. 1988	Core

Since the LC50 falls in the range of >1-10 ppm, imazalil is categorized as moderately toxic to freshwater fish on an acute basis. The guideline (72-1) is fulfilled (MRID 41606101/41606102).

### ii. Freshwater Fish, Chronic

A freshwater fish chronic toxicity studies are not required due to low acute toxicity and a minimal expected exposure.

### iii. Freshwater Invertebrates, Acute

A freshwater aquatic invertebrate toxicity test using the TGAI is required to establish the toxicity of imazalil to aquatic invertebrates. The preferred test species is *Daphnia magna*. Results of this test is tabulated below.

#### Freshwater Invertebrate Acute Toxicity

Species/Static or Flow- through	% ai	48-hour LC50/ EC50 (ppm)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea ( <i>Daphnia magna</i> )	97.6	3.54	Moderately toxic	41606103 Neytjens & Wils 1990	Core

Since the EC50 falls in the range of >1-10 ppm, imazalil is categorized as moderately toxic to aquatic invertebrates on an acute basis. The guideline (72-2) is fulfilled (MRID 41606103).

#### **iv. Freshwater Invertebrate, Chronic**

A freshwater aquatic invertebrate life-cycle test is not required due to relative low acute toxicities and a minimal expected exposure.

#### **v. Freshwater Field Studies**

Freshwater field study is not required due to expected minimal exposure.

#### **c. Toxicity to Estuarine and Marine Animals**

Estuarine and marine organisms toxicity studies are not required due to the expected minimal exposure.

#### **d. Toxicity to Plants**

Tier I aquatic plant growth studies (122-2) with two species of aquatic plants ( *Lema gibba* and *Selenastrum capricornutum* ) are required due to seed treatment end-use with soil incorporation application. These studies were waived previously, however, they are required under the current guidelines. These studies are still outstanding.

## APPENDIX 4: RQ CALCULATIONS SHEET

### 1. # of LD50/ft2

For typical in-furrow planting of seeds, 1% of seeds are assuming to be exposed on the surface

#### A) Birds

$$\text{LD50/ft}^2 = A/B = (\text{mg ai/ft}) / (\text{adj. LD50})$$

$$A = 0.01 \text{ lb ai} \times 0.01^* \times (453950 \text{ mg/lb} \div 43560 \text{ ft}^2) = \mathbf{0.001 \text{ mg/ft}^2}$$

$$\begin{aligned} B &= 2000^{**} \text{ mg/kg} \times 0.02 \text{ kg} = 40 \text{ mg/kg} && (\text{Adj. LD50 for song bird}) \\ &= 2000^{**} \text{ mg/kg} \times 0.18 \text{ kg} = 360 \text{ mg/kg} && (\text{Adj. LD50 for bobwhite quail}) \\ &= 2000^{**} \text{ mg/kg} \times 1.0 \text{ kg} = 2000 \text{ mg/kg} && (\text{Adj. LD50 for mallard duck}) \\ &\quad * 1 \% \text{ exposure on soil surface} \\ &\quad ** \text{ LD50 for r.n. pheasant} \end{aligned}$$

Therefore;

$$\text{LD50/ft}^2 (\text{songbird}) = 0.001 \text{ mg/ft}^2 \div 40 \text{ mg/kg} = \mathbf{0.00003 \text{ LD50/ft}^2}$$

$$\text{LD50/ft}^2 (\text{songbird}) = 0.001 \text{ mg/ft}^2 \div 360 \text{ mg/kg} = \mathbf{0.000003 \text{ LD50/ft}^2}$$

$$\text{LD50/ft}^2 (\text{songbird}) = 0.001 \text{ mg/ft}^2 \div 2000 \text{ mg/kg} = \mathbf{0.000001 \text{ LD50/ft}^2}$$

#### B) Mammals

$$\text{LD50/ft}^2 = A/B = (\text{mg ai/ft}) / (\text{adj. LD50})$$

$$A = 0.01 \text{ lb ai} \times 0.01^* \times (453950 \text{ mg/lb} \div 43560 \text{ ft}^2) = \mathbf{0.001 \text{ mg/ft}^2}$$

$$\begin{aligned} B &= 343 \text{ mg/kg} \times 0.015 \text{ kg} = \mathbf{5.145 \text{ mg/kg}} && (\text{Adj. LD50 for 15 g mammal}) \\ &= 343 \text{ mg/kg} \times 0.035 \text{ kg} = \mathbf{12.005 \text{ mg/kg}} && (\text{Adj. LD50 for 35 g mammal}) \\ &= 343 \text{ mg/kg} \times 1.0 \text{ kg} = \mathbf{343 \text{ mg/kg}} && (\text{Adj. LD50 for 1 kg mammal}) \end{aligned}$$

Therefore;

$$\text{LD50/ft}^2 (15 \text{ g mammal}) = 0.001 \text{ mg/ft}^2 \div 5.145 \text{ mg/kg} = \mathbf{0.0002 \text{ LD50/ft}^2}$$

$$\text{LD50/ft}^2 (35 \text{ g mammal}) = 0.001 \text{ mg/ft}^2 \div 12.005 \text{ mg/kg} = \mathbf{0.00008 \text{ LD50/ft}^2}$$

$$\text{LD50/ft}^2 (1 \text{ kg mammal}) = 0.001 \text{ mg/ft}^2 \div 343 \text{ mg/kg} = \mathbf{0.000003 \text{ LD50/ft}^2}$$

### 2. # of seeds / LD50)

#### A. Birds

$$\# \text{ of seeds/lb (wheat)} = (25 \text{ seeds/g}) \times (453.6 \text{ g/lb}) = \underline{11340} \text{ seeds/lb}$$

$$\# \text{ of seeds/lb (barley)} = (30 \text{ seeds/g}) \times (453.6 \text{ g/lb}) = \underline{13608} \text{ seeds/lb}$$

where 25 wheat seeds/g and 30 barley seeds/g

$$\begin{aligned}\# \text{ of seeds/A (wheat)} &= (11340 \text{ seeds /lb}) \times (100 \text{ lbs}) = 1134000 \text{ seeds/A} \\ \# \text{ of seeds/A (barley)} &= (13608 \text{ seeds/lb}) \times (100 \text{ lbs}) = 1360800 \text{ seeds/A}\end{aligned}$$

$$\begin{aligned}\text{mg ai/ seed (wheat)} &= 0.01 \text{ lb/A} \times (453950 \text{ mg/lb}) / (1134000 \text{ seeds/A}) = 0.004 \text{ mg ai/seed} \\ \text{mg ai/ seed (barley)} &= 0.01 \text{ lb/A} \times (453950 \text{ mg/lb}) / (1360800 \text{ seeds/A}) = 0.003 \text{ mg ai/seed}\end{aligned}$$

$$\begin{aligned}\# \text{ of seeds/LD50 (wheat)} &= (40 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{10000} && \mathbf{\text{Seeds/LD50 (song bird)}} \\ \# \text{ of seeds/LD50 (wheat)} &= (360 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{90000} && \mathbf{\text{Seeds/LD50 (bobwhite quail)}} \\ \# \text{ of seeds/LD50 (wheat)} &= (2000 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{500000} && \mathbf{\text{Seeds/LD50 (mallard duck)}} \\ \# \text{ of seeds/LD50 (barley)} &= (40 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{13333} && \mathbf{\text{Seeds/LD50 (song bird)}} \\ \# \text{ of seeds/LD50 (barley)} &= (360 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{120000} && \mathbf{\text{Seeds/LD50 (bobwhite quail)}} \\ \# \text{ of seeds/LD50 (barley)} &= (2000 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{666666} && \mathbf{\text{Seeds/LD50 (mallard duck)}}\end{aligned}$$

## B. Mammals

$$\begin{aligned}\# \text{ of seeds/lb (wheat)} &= (25 \text{ seeds/g}) \times (453.6 \text{ g/lb}) = \underline{11340} \text{ seeds/lb} \\ \# \text{ of seeds/lb (barley)} &= (30 \text{ seeds/g}) \times (453.6 \text{ g/lb}) = \underline{13608} \text{ seeds/lb}\end{aligned}$$

where 25 wheat seeds/g and 30 barley seeds/g

$$\begin{aligned}\# \text{ of seeds/A (wheat)} &= (11340 \text{ seeds /lb}) \times (100 \text{ lbs}) = 1134000 \text{ seeds/A} \\ \# \text{ of seeds/A (barley)} &= (13608 \text{ seeds/lb}) \times (100 \text{ lbs}) = 1360800 \text{ seeds/A}\end{aligned}$$

$$\begin{aligned}\text{mg ai/ seed (wheat)} &= 0.01 \text{ lb/A} \times (453950 \text{ mg/lb}) / (1134000 \text{ seeds/A}) = 0.004 \text{ mg ai/seed} \\ \text{mg ai/ seed (barley)} &= 0.01 \text{ lb/A} \times (453950 \text{ mg/lb}) / (1360800 \text{ seeds/A}) = 0.003 \text{ mg ai/seed}\end{aligned}$$

$$\begin{aligned}\# \text{ of seeds/LD50 (wheat)} &= (5.145 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{1286} && \mathbf{\text{Seeds/LD50 (15 g mammal)}} \\ \# \text{ of seeds/LD50 (wheat)} &= (12.005 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{3001} && \mathbf{\text{Seeds/LD50 (35 g mammal)}} \\ \# \text{ of seeds/LD50 (wheat)} &= (343 \text{ mg/kg}) \div (0.004 \text{ mg}) = \mathbf{85750} && \mathbf{\text{Seeds/LD50 (1 kg mammal)}} \\ \# \text{ of seeds/LD50 (barley)} &= (5.145 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{1715} && \mathbf{\text{Seeds/LD50 (15 g mammal)}} \\ \# \text{ of seeds/LD50 (barley)} &= (12.005 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{4002} && \mathbf{\text{Seeds/LD50 (35 g mammal)}} \\ \# \text{ of seeds/LD50 (barley)} &= (343 \text{ mg/kg}) \div (0.003 \text{ mg}) = \mathbf{114333} && \mathbf{\text{Seeds/LD50 (1 kg mammal)}}\end{aligned}$$

## 3. EEC/NOEC

RQ values for chronic toxicity studies are calculated assuming unlimited treated seeds available on soil surface and birds/mammals eating nothing but these seeds

$$\text{RQ EEC (residue in seed) / NOEC}$$

$$\text{where, residue in seed} = 0.01 \text{ lb ai/A} \div 100 \text{ lb seeds/A} = 0.0001 \text{ or } \mathbf{100 \text{ ppm}}$$

$$\text{RQ (bird)} = 100 \text{ ppm} \div 250 \text{ ppm} = \mathbf{0.4}$$

$$\text{RQ (mammal)} = 100 \text{ ppm} \div 300 \text{ ppm} = \mathbf{0.3}$$

## APPENDIX 5: EXPOSURE AND RISK TO NONTARGET ANIMALS

### Risk Assessment

A means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic.

$$RQ = \text{EXPOSURE/TOXICITY}$$

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories: (1) **acute high** - potential for acute risk is high, regulatory action may be warranted in addition to restricted use classification (2) **acute restricted use** - the potential for acute risk is high, but this may be mitigated through restricted use classification (3) **acute endangered species** - the potential for acute risk to endangered species is high, regulatory action may be warranted, and (4) **chronic risk** - the potential for chronic risk is high, regulatory action may be warranted. Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to nontarget insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic risk quotients are derived from the results of required studies. Examples of ecotoxicity values derived from the results of short-term laboratory studies that assess acute effects are: (1) LC50 (fish and birds) (2) LD50 (birds and mammals) (3) EC50 (aquatic plants and aquatic invertebrates) and (4) EC25 (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOEC (birds, fish, and aquatic invertebrates) (2) NOEC (birds, fish and aquatic invertebrates) and (3) MATC (fish and aquatic invertebrates). For birds, mammals, and all aquatic organisms, the NOEC is the ecotoxicity test value used in assessing chronic risk. Other values may be used when justified. Risk presumptions, along with the corresponding RQs and LOCs are summarized in **Tables 1** through **3**.

**Table 1. Risk presumptions for terrestrial animals**

<b>Risk Presumption</b>	<b>RQ</b>	<b>LOC</b>
<b>Birds</b>		
Acute High Risk	EEC <sup>1</sup> /LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day <sup>3</sup>	0.5
Acute Restricted Use	EEC/LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day (or LD <sub>50</sub> < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day	0.1
Chronic Risk	EEC/NOEC	1
<b>Wild Mammals</b>		
Acute High Risk	EEC/LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day	0.5
Acute Restricted Use	EEC/LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day (or LD <sub>50</sub> < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC <sub>50</sub> or LD <sub>50</sub> /ft <sup>2</sup> or LD <sub>50</sub> /day	0.1
Chronic Risk	EEC/NOEC	1

<sup>1</sup> abbreviation for Estimated Environmental Concentration (ppm) on avian/mammalian food items

<sup>2</sup>  $\frac{\text{mg}}{\text{ft}^2}$                       <sup>3</sup>  $\frac{\text{mg of toxicant consumed}}{\text{day}}$   
 LD50 \* wt. of bird                      LD50 \* wt. of bird

**Table 2. Risk presumptions for aquatic animals**

<b>Risk Presumption</b>	<b>RQ</b>	<b>LOC</b>
Acute High Risk	EEC <sup>1</sup> /LC <sub>50</sub> or EC <sub>50</sub>	0.5
Acute Restricted Use	EEC/LC <sub>50</sub> or EC <sub>50</sub>	0.1
Acute Endangered Species	EEC/LC <sub>50</sub> or EC <sub>50</sub>	0.05
Chronic Risk	EEC/NOEC	1

<sup>1</sup> EEC = (ppm or ppb) in water

**Table 3. Risk presumptions for plants**

<b>Risk Presumption</b>		<b>RQ</b>	<b>LOC</b>
Terrestrial and Semi-Aquatic Plants			
Acute High Risk	EEC <sup>1</sup> /EC <sub>25</sub>		1
Acute Endangered Species	EEC/EC <sub>05</sub> or NOEC		1
Aquatic Plants			
Acute High Risk	EEC <sup>2</sup> /EC <sub>50</sub>		1
Acute Endangered Species	EEC/EC <sub>05</sub> or NOEC		1

<sup>1</sup> EEC = lbs ai/A

<sup>2</sup> EEC = (ppb/ppm) in water